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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville, Maryland 20850

APR - 7 2003

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. John Remmers
President
SagaTech Electronics, Inc.
3413 8th Street S.E.
Calgary, Alberta
Canada T2G 3A4

Dear Mr. Remmers:

During an inspection of your firm in Calgary, Alberta, Canada, on December 2 through 5, 2002, our investigator determined that your firm manufactures the SnoreSat/Remmer Recorder. These products are medical devices under the Federal Food, Drug, and Cosmetic Act (the Act), because they are intended for use in diagnosing or treating a medical condition or to affect the structure or a function of the body (Section 201(h) of the Act, 21 U.S.C. § 321(h)).

The inspection revealed that these medical devices are adulterated within the meaning of section 501(h) of the Act (21 U.S.C. § 351(h)), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of FDA's Quality System (QS) regulation, in Title 21, Code of Federal Regulations (CFR), Part 820, as listed below:

1. Failure to establish and maintain adequate procedures to control the design of the device in order to ensure that specified requirements are met as required by 21 CFR 820.30(a). For example:

The design and development section in the firm's quality manual is only a plan. There are no procedures that compliment those instructions. No procedures were established, defined, or documented for the design and development of the device.

Your response of December 20, 2002, stated that procedures to fully comply with the provisions of the Quality System Regulation would be developed. You estimated that this would be accomplished by the end of February 2003. Your firm submitted a response dated February 24, 2003, stating that a design and development plan had been established and defined. In your response of February 28, 2003, your firm submitted a design and development plan.

This response is not adequate because what the firm identified as Design and Development Planning Standard Operating Procedures did not include sufficient detail or instructions to be effectively implemented by employees. The procedure provides an outline of requirements, but there is no instruction as to how to actually implement the procedure. The detail necessary to define what is to be done, who is responsible, and how it is to be completed is lacking. Additionally, you have not provided specific procedures for design validation, design verification, or design changes.

2. **Failure to establish and maintain adequate procedures for implementing corrective and preventive action as required by 21 CFR 820.100(a).** For example, customer returns and customer complaints are combined in one file. The firm's Quality Manual Complaint Handling Procedure states that the Quality Assurance Manager shall enter information into a complaint file log and initiate a corrective action to correct the problem. This procedure was not established and implemented.

In your response of December 20, 2002, your firm stated that procedures to fully comply with the provisions of the Quality System Regulation would be developed. You estimated that this would be accomplished by the end of February 2003. Your firm submitted a response dated February 24, 2003, stating that procedures for a corrective and preventive action (CAPA) plan have been established, defined, and documented. On February 28, 2003, your firm provided a Corrective and Preventive Action Procedure.

This response is not adequate. The procedure provides an outline of requirements, but there is no instruction as to how to actually implement the procedure. The detail necessary to define what is to be done, who is responsible, and how it is to be completed is lacking. Examples include, but are not limited to:

1. The procedure does not address validation of the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device. The procedure only specifies verification. To be complete, the procedure should also define when verification will be used instead of validation and require the scientific justification for this decision.

2. The procedure does not include any reference to a statistical methodology that is used to identify recurring problems or trends.

3. The procedure does not address the generation of documentation of any required changes to manufacturing processes.

4. The procedure does not assign priority levels to any potential problem. Section 2.3 states that "actions" shall be appropriate to the severity of the "problem" and proportionate to the "risks," but it fails to define these terms

5. Recalls or recall procedures are not addressed or linked to your CAPA procedure.

6. There is no discussion of how changes are to be disseminated. For example, is this to be done by memo, and how is it to be determined who is directly affected?

3. Failure to establish and maintain adequate procedures to ensure that any complaint that represents an event that must be reported to FDA shall be promptly reviewed, evaluated, and investigated by a designated individual(s) and shall be maintained in a separate portion of the complaint files or otherwise clearly identified in accordance with 21 CFR 820.198(d). For example, written procedures for medical device reporting (MDR) that would ensure the prompt identification, timely investigation, reporting, documentation, and filing of a device-related death, serious injury, and/or malfunction information, have not been established, documented, or implemented.

Your response of December 20, 2002, stated that procedures to fully comply with the provisions of the Quality System Regulation would be developed. You estimated that this would be accomplished by the end of February 2003. Your response of February 24, 2003, stated that a written procedure for medical device reporting had been established and documented. In your response of February 28, 2003, you submitted a procedure for medical device reporting.

A review of the response dated February 28, 2003, indicates it is not adequate. The procedure provides an outline of requirements, but there is no instruction as to how to actually implement the procedure. The detail necessary to define what is to be done, who is responsible and how it is to be completed is lacking. Additionally, the "or contributed to" concept is not covered. According to the regulation, if the device may have caused or contributed to serious injury or death then an MDR report should be filed. Your procedure only requires that reports be filed if the device caused a death or serious injury.

4. Failure to establish and maintain procedures for changes to a specification, method, process, or procedure to ensure that the device conforms to its specifications, as required by 21 CFR 820.70(b). For example, the test procedure for production of the main board did not show the engineering change orders that changed the test procedure for power consumption values.

In your response of December 20, 2002, your firm stated that procedures to fully comply with the provisions of the Quality System Regulation would be developed. You estimated that this would be accomplished by the end of February 2003. In your response of February 24, 2003, your firm indicated that you would complete your response by the end of March, 2003.

This response is not adequate. Please provide these procedures for our review when they are completed, ensuring that the procedure includes sufficient detail.

5. Failure to establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system as required by 21

CFR 820.22. For example, your firm does not have procedures for conducting quality audits.

In your response of December 20, 2002, your firm stated procedures to fully comply with the provisions of the Quality System Regulation would be developed. You estimated this would be accomplished by the end of February 2003. In your response of February 24, 2003, your firm stated that written procedures for conducting management reviews and quality audits had been established and documented. On February 28, 2003, your firm provided a quality audit procedure.

This response is not adequate. The procedure provides an outline of requirements, but there is no instruction as to how to actually implement the procedure. The detail necessary to define what is to be done, who is responsible and how it is to be completed is lacking. For example, the procedure does not indicate that a copy of the audit results is to be given to the area that is being audited, nor does the procedure ensure that all procedures will be evaluated as part of the quality audit.

6. Failure to review the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency according to established procedures as required by 21 CFR 820.20(c). For example, your firm does not have procedures for conducting management reviews.

In your response of December 20, 2002, your firm stated procedures to fully comply with the provisions of the Quality System Regulation would be developed. You estimated this would be accomplished by the end of February 2003. In your response of February 24, 2003, your firm stated that written procedures for conducting management reviews and quality audits had been established and documented. On February 28, 2003, your firm provided a management review procedure.

This response is not adequate. The procedure provides an outline of requirements, but there is no instruction as to how to actually implement the procedure. The detail necessary to define what is to be done, who is responsible, and how it is to be completed is lacking. For example, it is indicated that management will review consumer complaints, but it does not specify if management is reviewing a summary of complaints received, each individual complaint, randomly selected complaints, etc.

Additionally, in the premarket notification (510(k)) that you submitted to the agency, you provided a certification that your device would be tested for electromagnetic compatibility testing (emissions and immunity). Please provide the results of this testing in your response to this letter.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the

causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

We acknowledge that you have submitted to this office responses dated December 20, 2002, February 24, 2003, and February 28, 2003 concerning our investigator's observations noted on the form FDA 483. We have reviewed your responses and have concluded that they are inadequate. An evaluation of specific responses is entered after each one of the deviations listed above.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected.

Given the serious nature of these violations of the Act, the ventilatory effect recorders manufactured at this facility may be detained without physical examination upon entry into the United States. In order to prevent your devices from being detained without physical examination, your firm will need to respond to this Warning Letter (as set forth below) and correct the violations noted in this letter. In addition, the agency usually needs to conduct a follow-up inspection to verify that the appropriate corrections have been implemented.

Please notify this office in writing of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. Please include any and all documentation to show that adequate correction has been achieved. In the case of future corrections, an estimated date of completion, and documentation showing plans for correction should be included with your response to this letter. If the documentation is not in English, please provide a translation to facilitate our review.

Your response should be sent to:

Christy Foreman, Branch Chief
Division of Enforcement B (HFZ-343)
Office of Compliance
Center for Devices and Radiological Health
2094 Gaither Rd.
Rockville, MD 20850

If you have any questions about the contents of this letter, please contact Mr. James Eisele at the above address or at (301) 594-4659, or fax (301) 594-4672. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers International and Consumer Assistance at (301) 443-6597, or through the Internet at **http://www.fda.gov**.

Sincerely yours,

Gladys Rodriguez

for Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health